SH

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 14-R-0035

Customer Number: 130

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

University Of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Telephone: (508) 856 3151

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OCT 22 2009
BY

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)*

FACILITY LOCATIONS *(Sites)* *See Attached Listing*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs		-0-	13	-0-	13
5. Cats		-0-	-0-	-0-	-0-
6. Guinea Pigs		430	276	359	1065
7. Hamsters		57	70	-0-	-0-
8. Rabbits		23	147	-0-	170
9. Non-human Primates		-0-	-0-	-0-	-0-
10. Sheep		-0-	-0-	-0-	-0-
11. Pigs		3	51	-0-	54
12. Other Farm Animals		-0-	-0-	-0-	-0-
13. Other Animals		-0-	-0-	-0-	-0-

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)c

DATE SIGNED 10/15/2009

APHIS FORM 7023
AUG 2009

EE 12-3-09

University of Massachusetts Medical School
Registration Number: 12-R-0035

Category E Explanations

Tested: Tetanus and Diptheria Toxoids.
Number used: 359
Species: Guinea pig

Explanation
*Category E in vivo testing performed on Dockets A-1101, Potency, and MLD testing, A-1122, and A-1137 at the (b)(2)High, (b)(7)f located at the University of Massachusetts Medical School (b)(2)High, (b)(7)f are death as an endpoint mandated assays. MLD testing is required per US Dept. HEW, PHS, NIH Minimum requirements: Section 1.3., 4th revision, March 1, 1947, stipulating both parent toxins, Tetanus and Diphtheria must be evaluated prior to toxoiding. Because tetanospasmin is a neurotoxin without measureable cytotoxicity, the MLD is the only available tool to achieve the goals prescribed by regulation and licensure.

The potency test in vaccine products, including Td (Multi-dose) and Preservative Free Td, is performed in accordance with the NIH Minimum Requirements: Tetanus Toxoid, Section 3.3, 4th Revision, December 15, 1952 and NIH Minimum Requirements: Tetanus and Diphtheria Toxoids Combined Precipitated Adsorbed (For Adult Use), August 25, 1953. The potency test for the corresponding AK component associated with each product, is performed in accordance with the NIH Minimum Requirements, previously noted, and NIH Minimum Requirements: Tetanus and Diphtheria Toxoids Combined Precipitated Adsorbed (For Adult Use), Amendment No. 1, November 28, 1956.